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**UNITED STATES DISTRICT COURT  
CENTRAL DISTRICT OF CALIFORNIA**

K.S., individually and on behalf of all  
others similarly situated,

Plaintiffs,

vs.

FUJIFILM IRVINE SCIENTIFIC, INC.,  
FUJIFILM HOLDINGS AMERICA  
CORP., and DOES 1-10, inclusive,

Defendants.

CASE NO.: 8:24-CV-02589

**COMPLAINT (CLASS ACTION)**

1. Strict Product Liability—  
Manufacturing Defect;
2. Strict Product Liability—Failure to  
Warn;
3. Negligent Failure to Recall;
4. Trespass to Chattels;
5. Unjust Enrichment.

(Jury Trial Demanded)

1 Plaintiff K.S. (“Plaintiff”), by and through her undersigned counsel, bring this  
2 Class Action Complaint on behalf of herself and a class of similarly situated individuals  
3 against FUJIFILM Irvine Scientific, Inc. and FUJIFILM Holdings America Corporation  
4 (collectively, “Defendants” or “Irvine Scientific”). Plaintiff bases her allegations upon  
5 her personal knowledge, information and belief, and the investigation of counsel, and  
6 allege as follows:

## 7 INTRODUCTION

8 1. Plaintiff brings this Class action against Irvine Scientific, the manufacturer  
9 of various products used in fertility treatment and women’s health. Irvine Scientific  
10 manufactures a mineral oil, intended to be used in tandem with medium for culturing  
11 embryos, that is, a solution in which fertilized embryos (starting at just a single cell)  
12 develop sufficiently to be transferred to a patient’s uterus to facilitate pregnancy.

13 2. The stage at which embryos are cultured is one of the final stages of an  
14 intensive, invasive, emotionally tolling, and expensive fertility treatment program, *in*  
15 *vitro* fertilization or “IVF.” IVF is one of the most common fertility treatments for all  
16 types of infertility and has been used to assist patients in obtaining a successful pregnancy  
17 for nearly fifty years.

18 3. IVF is, itself, an emotionally tolling and burdensome process. Patients are  
19 strictly monitored and placed on a highly regimented medication schedule, most of which  
20 require daily injections, frequent doctors’ visits, and numerous ultrasounds, among other  
21 procedures. The effort culminates in two significant procedures—the “retrieval”, where  
22 follicles that have matured in eggs are collected and removed from a patient’s ovaries,  
23 and the “transfer”, when a sufficiently developed embryo (or sometimes, embryos) are  
24 placed in the patient’s uterus in hopes of facilitating a successful pregnancy and,  
25 ultimately, birth.

26 4. Between the two milestones of retrieval and transfer, fertility clinics perform  
27 techniques to fertilize the collected eggs and grow them to the blastocyte stage, where  
28 the embryo has sufficiently developed to attempt the transfer. This 5–6-day period occurs

1 at the very end of IVF, after patients expended time, effort, and significant expense.  
2 Patients have already learned the number of fertilized eggs and, for nearly a week, wait  
3 to hear if their embryos are ready for transfer.

4 5. The technique used to culture and grow embryos requires use of a medium,  
5 or solution, that provides the appropriate environment and nutrients for the embryos to  
6 grow and mature. Irvine Scientific's mineral oil, which it calls Oil for Embryo Culture  
7 ("Oil"), is used along with the medium to culture embryos to the blastocyst stage and  
8 prepare them for transfer. The Oil is used "as an overlay...to prevent evaporation, and to  
9 protect the media from changes in osmolality and pH."<sup>1</sup>

10 6. Understandably, for patients, this stage is dramatic, tense, and stressful. With  
11 hope and pregnancy peeking around the corner, however, hundreds of fertility patients,  
12 including Plaintiff and the Class, learned that their embryos were irrevocably damaged  
13 and lost in the process.

14 7. On January 16, 2023, those patients learned why. Irvine Scientific's Oil for  
15 Embryo Culture had been shipped to fertility clinics throughout the United States with a  
16 serious and consequential defect. Rather than providing the protection and stability  
17 required for embryo growth, Irvine Scientific's defective Oil for Embryo Culture created  
18 an environment where embryos would, instead, be destroyed. It issued a notice and,  
19 subsequently, a recall of the defective Oil for Embryo Culture.

20 8. However, for Plaintiff and the Class, those patients whose embryos had been  
21 cultured with the defective Oil for Embryo Culture, the recall was too late. The Oil for  
22 Embryo Culture had already finally ruined their embryos, thwarting the immense effort  
23 and expense of patients' IVF treatment and crushing patients' hopes for pregnancy and a  
24 child.

25 9. Understandably, the emotional toll of losing an embryo at the very last stage  
26 before transfer is significant, and such loss is associated with high rates of depression,

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28 <sup>1</sup> *Oil for Embryo Culture*, FUJIFILM IRVINE SCI., <https://www.irvinesci.com/oil-for-embryo-culture.html> (last visited Aug. 20, 2024).

1 anxiety, and other mental health issues. Moreover, patients must repeat the difficult,  
2 burdensome, and costly IVF treatment to pursue a pregnancy or abandon their hopes  
3 altogether. Even those who do repeat IVF face the chance that no eggs will be retrieved  
4 or fertilized.

5 10. Irvine Scientific knew or should have known of the significant economic  
6 and emotional toll imposed on fertility patients through its manufacturing, selling, and  
7 shipping of defective Oil for Embryo Culture to fertility clinics. Given that substantial  
8 and foreseeable risk, Irvine Scientific had a duty to reasonably manufacture its Oil for  
9 Embryo Culture and implement quality control measures to inspect, test, and ensure that  
10 its Oil met the required specifications.

11 11. Irvine Scientific, however, breached that duty, failing to inspect over 15,000  
12 bottles of its defective Oil for Embryo Culture that were manufactured and prepared for  
13 use on fertility patients' embryos. Indeed, Irvine Scientific failed to identify the issue on  
14 its own at all, becoming aware that its Oil for Embryo Culture was destroying embryos  
15 from its customers. By that point, irreparable damage was done to likely hundreds of  
16 embryos that were impaired, damaged, and lost.

17 12. Plaintiff brings claims on behalf of a Nationwide Class and a Arizona  
18 Subclass of fertility patients whose embryos were impacted by the defective Oil for  
19 Embryo Culture. Plaintiff and the Class seek to recover for the expense of IVF wasted  
20 when, at the very last stages, Irvine Scientific's defective Oil ruined the embryos that  
21 were developed, matured, and fertilized throughout the burdensome process. Plaintiff  
22 also seeks to recover for their lost and damaged embryos, which were irreparably harmed  
23 by the Oil for Embryo Culture, ruining the opportunity to bring those embryos to life.  
24 Finally, Plaintiff seeks to recover for the significant and lasting emotional harm caused  
25 by the loss of one or more embryos. Plaintiff brings claims for Strict Liability for a  
26 Manufacturing Defect, Strict Liability for Failure to Warn, Negligence, Negligent Failure  
27 to Recall, Trespass of Chattel, and Unjust Enrichment.

## JURISDICTION AND VENUE

13. This Court has subject matter jurisdiction under the Class Action Fairness Act (“CAFA”), 28 U.S.C. § 1332(d). As required under CAFA, Plaintiff is a citizen of a state different from both Defendants, the amount in controversy exceeds \$5,000,000, excluding interest and costs, and the proposed class consists of more than 100 individuals.

14. This Court has personal jurisdiction over Defendants. Defendants conduct substantial business in this District and intentionally availed itself of the laws and markets of this District. Defendant FUJIFILM Irvine Scientific, Inc. also has its headquarters located in this District. A significant portion of the acts and omissions complained of occurred in the District.

15. Venue is proper in this District under 28 U.S.C. § 1391 because Defendant FUJIFILM Irvine Scientific, Inc. resides in this District and a substantial part of the events or omissions giving rise to this action occurred in this District.

## PARTIES

16. **Plaintiff** K.S. is a resident of North Dakota who obtained fertility treatment, including IVF treatment, from Arizona Reproductive Medicine in Phoenix, Arizona. K.S.’s clinic confirmed it used the defective Oil during her IVF treatment while culturing her fertilized embryos.

17. **Defendant** FUJIFILM Irvine Scientific, Inc., a wholly owned subsidiary of FUJIFILM Corporation, is a California corporation with its principal place of business in Santa Ana, California.

18. **Defendant** FUJIFILM Holdings America Corporation is a Delaware corporation with its principal place of business in Valhalla, New York. It is the sole owner of FUJIFILM Irvine Scientific, Inc. FUJIFILM Holdings America Corp. takes substantial actions in this District with respect to its oversight of FUJIFILM Irvine Scientific, Inc.

## FACTUAL ALLEGATIONS

### A. In-Vitro Fertilization: the “First Line” Infertility Treatment

19. Each year, hundreds of thousands of patients seek fertility treatment due to complications achieving or maintaining a pregnancy.

20. The National Institutes of Health estimates that 9% of men and 11% of women of reproductive age in the United States experience fertility problems.<sup>2</sup> Approximately 10% of couples are estimated to be unable to conceive naturally,<sup>3</sup> and that number increases with the age of the couples.<sup>4</sup> Some studies suggest that rate of infertility is increasing in the United States, including, in part, because couples now have children later.<sup>5</sup> The rate of infertility for women 30–39 is nearly double the rate of women under 30.<sup>6</sup>

21. With rising infertility and development of new technologies and methods to assist in achieving a pregnancy, the use of fertility treatments has grown.<sup>7</sup> Approximately four in ten adults have used fertility treatments or personally know someone who has, a rate that has grown substantially from just five years ago.<sup>8</sup> As of 2017, over 1 million babies were born in the United States through the use of IVF or other assisted reproductive technologies.<sup>9</sup>

22. Although fertility treatments vary depending on the cause of infertility, one of the most common methods of assisting a pregnancy is *in vitro* fertilization or “IVF.”

<sup>2</sup> *How Common is Infertility?*, NAT’L INST. HEALTH, <https://www.nichd.nih.gov/health/topics/infertility/conditioninfo/common> (last visited Aug. 21, 2024).

<sup>3</sup> *Id.*

<sup>4</sup> *Is Infertility on the Rise?*, CCRM FERTILITY (June 16, 2022), <https://www.ccrmivf.com/blog/is-infertility-on-the-rise>.

<sup>5</sup> *Id.*

<sup>6</sup> *Id.*

<sup>7</sup> Isabel Goddard & Carolina Aragão, *A Growing Share of Americans Say They’ve Had Fertility Treatments or Know Someone Who Has*, PEW RSCH. CTR. (Sept. 14, 2023), <https://www.pewresearch.org/short-reads/2023/09/14/a-growing-share-of-americans-say-theyve-had-fertility-treatments-or-know-someone-who-has>.

<sup>8</sup> *Id.*

<sup>9</sup> *IVF By the Numbers*, PENN MED. FERTILITY BLOG (Mar. 14, 2018), <https://www.pennmedicine.org/updates/blogs/fertility-blog/2018/march/ivf-by-the-numbers>.

1 IVF is considered the first line therapy for all causes of infertility<sup>10</sup> and is the leading  
2 treatment for several prevalent causes of infertility, including damaged fallopian tubes,  
3 unexplained fertility issues, and male-factor infertility.<sup>11</sup>

4 23. IVF is also used by couples seeking to prevent passing on dangerous or  
5 deadly genetic conditions. Upon achieving a successful IVF cycle, the blastocytes (or  
6 developed embryos) are genetically tested to identify any potentially fatal or debilitating  
7 traits. For instance, carriers of genetic conditions seek to avoid passing on fatal disease  
8 to their children, including Krabbe Leukodystrophy or Tay-Sachs disease (fatal  
9 conditions in newborns or toddlers) or Huntington's disease (fatal in adults in their 30s  
10 and 40s). Some couples also use IVF to prevent passing on genetic conditions that impose  
11 severe cognitive, behavioral, or physical disabilities.

12 24. IVF treatment involves intense and invasive monitoring and maintenance of  
13 a patient's ovulatory process to stimulate egg development and sophisticated laboratory  
14 techniques designed to fertilize the eggs and develop the embryos. All is done with the  
15 hope of obtaining embryos that develop sufficiently to the "blastocyte" stage, where they  
16 are ready to be transferred to the patient for a potential pregnancy.

17 25. In all, a single IVF cycle involves several steps: (1) patients take fertility  
18 drugs to stimulate ovaries to develop follicles which mature into eggs; (2) patients  
19 undergo a "retrieval" surgery, during which the eggs are obtained from the patient; (3)  
20 the eggs are then fertilized with sperm, creating embryos; (4) the embryos are cultured  
21 using media, with the goal of developing the egg over the course of five days; and (5) the  
22 cultured embryos, called blastocytes, are transferred to the patient's uterus in an attempt  
23 at pregnancy.

24 26. IVF requires enormous costs and effort by fertility patients, and often, little  
25 to none of the medical costs associated with IVF are covered by insurance. With medical  
26 and pharmaceutical costs, the average IVF cycle costs patients upwards of at least

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27 <sup>10</sup> *Id.*

28 <sup>11</sup> *Id.*



1 \$25,000 for a single round of treatment. Many patients, however, also incur costs for  
2 additional treatments, including genetic testing of the embryos (because IVF is often used  
3 to eliminate or avoid passing on deadly or dangerous conditions) or other surgical  
4 procedures.

5 27. Moreover, IVF requires an intense and lengthy regimen of medications and  
6 doctor visits to ensure the follicles develop appropriately, to time the retrieval, and to  
7 facilitate fertilization and embryo growth. During a single IVF cycle, patients take  
8 medication daily, often including hormones administered through injections. The  
9 injections can cause a host of side significant effects, including, among other things, pain  
10 and discomfort. While follicles are developing, patients must undergo frequent medical  
11 testing and monitoring by their physicians and fertility care team, often requiring daily  
12 doctor visits and ultrasounds to monitor the progress of follicle development and to  
13 determine the appropriate time for retrieval.

14 28. Fertility patients may also experience Ovarian Hyperstimulation Syndrome,  
15 an extreme response to excess hormones often caused by the medications taken to trigger  
16 a retrieval. Ovarian Hyperstimulation syndrome can cause serious complications,  
17 including abdominal bloating and pain, blood clots, shortness of breath, rapid weight  
18 gain, and even death. Severe cases of Ovarian Hyperstimulation Syndrome require  
19 hospitalization, and the symptoms can last several weeks.

20 29. Even when retrieval and fertilization of the embryos is successful, patients  
21 must still wait for the embryos to develop. Over the course of five to seven days, embryos  
22 are cultured in a media created specifically to promote the growth of the embryo into a  
23 blastocyte stage. That is, developing the fertilized embryo from a single cell into  
24 approximately one hundred cells.

25 30. Embryos that make it to the blastocyte stage are generally given grades  
26 based on the quality and size, so that the embryos most likely to result in a pregnancy  
27 may be transferred. When an embryo makes it to the blastocyte stage, it may be: (1)  
28 transferred immediately to the patient to attempt a pregnancy, known as a “fresh transfer”;



(2) frozen and saved for use in a later attempt at a pregnancy, known as a “frozen transfer”; or (3) be biopsied for genetic testing of the embryo.

31. As such, patients may proceed through several cycles before experiencing a successful pregnancy or pursuing an alternative path for building a family, including, for example, adoption or the use of a surrogate. Thus, while patients pay tens of thousands of dollars for a single cycle, patients in some cases incur hundreds of thousands of dollars in IVF treatment costs in hopes of achieving a pregnancy.

32. Consequently, IVF patients face a significant financial burden and emotional toll, due both to the IVF treatment and process itself and to the fertility complications or genetic risk factors that prompt IVF treatment.

### **B. Irvine Scientific’s Fertility and IVF-Related Products**

33. Irvine Scientific claims to be a “worldwide leader in the innovation and manufacture of cell culture media, reagents, and medical devices.”<sup>12</sup> It offers a wide range of medical products and claims to “dedicate [its] resources and expertise to help [ ] successfully fulfill [ ] patients’ dreams of having a family.”<sup>13</sup>

34. Among Irvine Scientific’s fertility-related products is Oil for Embryo Culture, described as a “sterile light mineral oil intended for use as an overlay when culturing in reduced volumes of media.”<sup>14</sup> Irvine Scientific acknowledges that “[r]eproductive media products play an important role in helping to foster life at the most vulnerable phases of development.”<sup>15</sup>

35. Embryo culture media and the Oil for Embryo Culture are used at the tail end of IVF treatment. That is, Irvine Scientific’s Oil for Embryo Culture is used after all the injections, oral and suppository medications, and doctor appointments led to the

<sup>12</sup> *About Us*, FUJIFILM IRVINE SCI., <https://www.irvinesci.com/about-us> (last visited Aug. 21, 2024).

<sup>13</sup> *Assisted Reproductive Technology*, FUJIFILM IRVINE SCI., <https://www.irvinesci.com/assisted-reproductive-technology> (last visited Aug. 21, 2024).

<sup>14</sup> *Oil for Embryo Culture*, FUJIFILM IRVINE SCI., <https://www.irvinesci.com/assisted-reproductive-technology/protein-supplements-oils/oil-for-embryo-culture.html> (last visited Aug. 21, 2024).

<sup>15</sup> *Assisted Reproductive Technology*, *supra* note 13.

1 development of follicles, retrieval of embryos, and fertilization of the eggs. The last step  
2 before transfer—that attempt at a pregnancy—involves the culturing of the fertilized  
3 embryos using the Oil for Embryo Culture with the hope of growing to the blastocyte  
4 stage where a transfer is possible.

5 36. The goal of embryo culture media is to improve the quality of the developing  
6 embryos and increase the chances of developing a viable embryo. The culture medium is  
7 designed to mimic the composition of the oviduct and uterine fluids to approximate the  
8 natural environment of the developing embryo. Culture media are “key components of  
9 culture systems” and many factors, including osmolality and pH stability, contribute to  
10 the stability of the culture environment.<sup>16</sup> Oil overlays, such as Irvine Scientific’s Oil for  
11 Embryo Culture, “represent[ ] a fundamental component of culture systems,” preventing  
12 culture medium evaporation as well as preserving proper pH and osmotic pressure.<sup>17</sup> Oil  
13 overlays further serve as “a physical barrier protecting culture media from toxic  
14 compounds and microorganism contamination.”<sup>18</sup>

15 37. Studies in recent years “have demonstrated how oil is crucial for embryo  
16 culture.”<sup>19</sup> Irvine Scientific is aware of the significance of high-quality culture  
17 environments on embryo development and the risk that unstable conditions and  
18 contaminants have on the development of embryos and the success of a transfer. Indeed,  
19 the product insert for Irvine Scientific’s Oil for Embryo Culture explains that the use of  
20 an oil overlay “is recommended...to prevent evaporation and to insulate the media from  
21 changes to osmolality and pH” and provides strict instructions to ensure the product is  
22 effective.<sup>20</sup>

23 <sup>16</sup> Catello Scarica et al., *Use of Mineral Oil in IVF Culture Systems: Physio-Chemical Aspects,*  
24 *Management, and Safety*, 39 J. ASSISTED REPROD. & GENETICS 883, 883–84 (2022), available  
at

25 [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9050982/pdf/10815\\_2022\\_Article\\_2479.pdf](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9050982/pdf/10815_2022_Article_2479.pdf)

26 <sup>17</sup> *Id.* at 884.

27 <sup>18</sup> *Id.*

28 <sup>19</sup> *Id.*

<sup>20</sup> OIL FOR EMBRYO CULTURE, FUJIFILM IRVINE SCIENTIFIC (2023), available at  
[https://www.irvinesci.com/media/IrvineScientific/Resources/4/0/40673\\_oil\\_for\\_embryo\\_9305.](https://www.irvinesci.com/media/IrvineScientific/Resources/4/0/40673_oil_for_embryo_9305.pdf)  
pdf.

1           **C. Irvine Scientific's Destructive Oil and Recall**

2           38. Although Irvine Scientific understood the importance of its Oil for Embryo  
3 Culture for the development of embryos and the need for high quality culture  
4 environments for embryos to develop, Irvine Scientific inexplicably failed to produce and  
5 distribute a product that met these standards.

6           39. On January 16, 2023, Irvine Scientific emailed an "URGENT: MEDICAL  
7 DEVICE RECALL" Letter to its customers (the fertility clinics) for its Oil for Embryo  
8 Culture product. In the letter, Irvine Scientific stated that it had "received complaints of  
9 reduced blastocyst development, including complete degradation."<sup>21</sup> Irvine Scientific  
10 instructed its customers to quarantine the affected product, return or destroy the product,  
11 and respond to the recall notice.

12           40. According to regulatory authorities, Irvine Scientific issued the recall due to  
13 the detection of oil toxicity in several lots of Oil for Embryo Culture products.<sup>22</sup> Irvine  
14 Scientific knew or should have known about the toxicity of its products. It, furthermore,  
15 should have known that oil toxicity in its Oil for Embryo Culture would destroy or  
16 irreparably impair the embryos.

17           41. Irvine Scientific, however, failed to adequately monitor its manufacturing  
18 systems and processes and to implement quality control measures necessary to ensure  
19 that its Oil for Embryo Culture was safe and effective for culturing embryos. Indeed,  
20 Irvine Scientific failed to detect the oil toxicity in its product until long after it had been  
21 shipped to its clients and used on patients. Irvine Scientific learned of the toxicity only  
22 after numerous patients suffered unexpectedly high rates of embryo loss, prompting the  
23 clinics to issue complaints and concerns to Irvine Scientific directly.

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26  
27 <sup>21</sup> See U.S. FOOD & DRUG ADMIN., CLASS 2 DEVICE RECALL FUJIFILM OIL FOR EMBRYO  
28 CULTURE (Jan. 16, 2023), *available at*  
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=198174>.

<sup>22</sup> *Id.*

1 42. Irvine Scientific failed to properly test or inspect the impacted lots of Oil for  
2 Embryo Culture. Consequently, approximately over 15,000 bottles of the Oil were  
3 affected and purchased by clinics for use in culturing embryos.

4 **D. Irvine Scientific's Oil for Embryo Culture Substantially Harmed**  
5 **Fertility Patients**

6 43. Irvine Scientific knew or should have known that defective oil overlays  
7 would impose significant emotional pain and suffering on the IVF patients whose  
8 embryos used the solution and would furthermore undermine the thousands of dollars  
9 and substantial time and effort the fertility patients expended during their IVF cycles.

10 44. Infertile couples, even before attempting IVF, experience significant  
11 anxiety and emotional distress.<sup>23</sup> The IVF process itself also imposes substantial burdens  
12 on couples, including significant financial obligations, frequent invasive medical  
13 procedures, and substantial stress and anxiety associated with the outcomes of the IVF  
14 cycle.

15 45. At the point where Irvine Scientific's Oil for Embryo Culture was used,  
16 fertility patients had reached the very end of their IVF treatment, with the next stage a  
17 transfer and potential pregnancy. With the eggs retrieved and fertilized, patients whose  
18 embryos were impaired with Irvine Scientific's defective product were on the last step  
19 before being able to attempt a transfer. Consequently, Irvine Scientific's defective  
20 product ruined the significant expense, time, and effort the fertility patients to make it to  
21 that final step.

22 46. In addition to the lost value of their IVF treatment, patients also suffered  
23 emotional harm, distress, and trauma. The loss of an embryo at the end of IVF treatment  
24 eviscerates the hope and excitement of a long-awaited pregnancy. As one practitioner  
25 explains, "[l]osing a pregnancy is losing a child" and the anxiety and depression from

26 <sup>23</sup> *Infertility and Mental Health*, CEDARS-SINAI BLOG (Sept. 8, 2020), <https://www.cedars-sinai.org/blog/infertility-mental-health.html#:~:text=Studies%20have%20shown%20that%20infertile,feelings%20of%20grief%20and%20loss.>  
27  
28

1 such a loss can last well over a year.<sup>24</sup> Furthermore, those “feelings can be especially  
2 intense if the pregnancy was long-awaited.”<sup>25</sup>

3 47. Over 55% of women present with depression after spontaneous loss of a  
4 pregnancy, exacerbating the pain and suffering IVF patients likely experienced from their  
5 difficulties with infertility. For those who have experienced recurrent pregnancy loss,  
6 many experience severe depression and high levels of stress, and their mental health is  
7 often negatively impacted even if they obtain a subsequent pregnancy.<sup>26</sup>

8 48. Ultimately, the loss of an embryo is the loss of a child. It is the loss of a  
9 potential pregnancy that, for IVF patients, has been elusive, turning a joyful opportunity  
10 into tragic loss. Irvine Scientific’s Oil for Embryo Culture carelessly and tragically ruined  
11 the chance of pregnancy and eroded and undermined the pain, suffering, expense, and  
12 effort IVF patients incurred for that chance.

13 49. As others in the field have recognized, “[f]ertility issues can affect your self-  
14 esteem, relationship, your emotional well-being and may even cause depression.”<sup>27</sup>  
15 Indeed, “[n]egative pregnancy tests, failed cycles” can lead to a host of harms and it listed  
16 several, including: (1) anxiety or feeling of anxiousness; (2) changes in appetite, weight,  
17 or sleep patterns; (3) difficulty concentrating; (4) difficulty maintaining social  
18 relationships; (5) frequently crying; (6) loss of appetite; (7) loss of interest in usual  
19 activities and relationships; (8) mood swings; (9) persistent feelings of sadness or guilt;  
20 (10) preoccupations with infertility; (11) suicidal thoughts or thoughts of self-harm.<sup>28</sup>

21  
22 <sup>24</sup> *Emotional Healing After a Miscarriage: A Guide for Women, Partners, Family, and Friends*,  
23 NURSING@GEORGETOWN BLOG (Mar. 5, 2020),  
24 [https://online.nursing.georgetown.edu/blog/emotional-healing-after-miscarriage-guide-](https://online.nursing.georgetown.edu/blog/emotional-healing-after-miscarriage-guide-women-partners-family-friends/#:~:text=Depression%20and%20anxiety%20are%20common,the%20pregnancy%20was%20long%2Dawaited.)  
25 [women-partners-family-friends/#:~:text=Depression%20and%20anxiety%20are%20common,the%20pregnancy%20was%20long%2Dawaited.](https://online.nursing.georgetown.edu/blog/emotional-healing-after-miscarriage-guide-women-partners-family-friends/#:~:text=Depression%20and%20anxiety%20are%20common,the%20pregnancy%20was%20long%2Dawaited.)

26 <sup>25</sup> *Id.*

27 <sup>26</sup> See Diana Cuenca, *Pregnancy Loss: Consequences for Mental Health*, 3 FRONTIERS IN GLOB.  
28 WOMEN’S HEALTH 1 (2022), available at  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9937061>.

<sup>27</sup> <https://www.coopersurgical.com/patient-article/can-infertility-support-groups-help-you/>

<sup>28</sup> *Id.*

1           50. Moreover, “[e]specially for women, not only do they have to deal with their  
2       grief and come to terms with the miscarriage, but they also have to manage the physical  
3       aspect of their loss.”<sup>29</sup>

4           51. Irvine Scientific, therefore, knew or should have known of the significant  
5       emotional and financial consequences imposed by the loss of an embryo. Despite that,  
6       Irvine Scientific’s defective solution, however, imposed the same harm, emotional loss,  
7       and grief on Plaintiff and the Class.

8           **E. Irvine Scientific Imposed Significant Harm on Plaintiff**

9           **1. Plaintiff K.S.**

10          52. Plaintiff K.S. obtained fertility treatment at Arizona Reproductive Medicine  
11       in Phoenix, Arizona. As part of that treatment, K.S. underwent IVF treatment. K.S.  
12       completed each stage of IVF treatment, proceeding through the costly, physically taxing,  
13       and emotionally burdensome process because it gave the opportunity to fulfill her hope  
14       of having a child.

15          53. During K.S.’s retrieval, her physicians collected three eggs, two of which  
16       were successfully fertilized, giving her two chances at a developed embryo to be used in  
17       a transfer for an attempted pregnancy.

18          54. Her fertility clinic used Irvine Scientific’s Oil for Embryo Culture while  
19       culturing the embryos after retrieval. Unfortunately, the clinic received some of the  
20       defective batch of Oil and used that Oil while culturing K.S.’s embryos. Consequently,  
21       all her embryos were lost.

22          55. Plaintiff, understandably, was devastated by the unexpected and complete  
23       loss of her embryos, which occurred in the very final stage before transfer. The loss of  
24       her embryos not only thwarted the time, effort, and expense of her IVF cycle, it imposed  
25       significant emotional harm and distress due both to the shock and grief over the loss of  
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28       <sup>29</sup> *Id.*

1 her embryos and the fear, anxiety, and hopelessness caused from the possibility she may  
2 have lost her opportunity to have children.

3 56. Plaintiff seeks all damages, equitable relief, and remedies available under  
4 the law due to the loss of her embryos caused by Irvine Scientific's defective Oil for  
5 Embryo Culture.

6 **CLASS ALLEGATIONS**

7 57. Plaintiff brings this action on behalf of herself and all other similarly situated  
8 Class members pursuant to Rule 23(a), (b)(2) and (b)(3) of the Federal Rules of Civil  
9 Procedure and seek certification of the following Nationwide Class:

10 All individuals in the United States who had one or more embryos cultured  
11 using any of the lots of Irvine Scientific's Oil for Embryo Culture identified  
12 in the April 1, 2023 Class 2 Device Recall FujiFilm Oil for Embryo Culture  
notice.

13 58. Excluded from the class is Irvine Scientific and its subsidiaries and affiliates;  
14 all employees of Irvine Scientific; all persons who make a timely election to be excluded  
15 from the class; government entities; and the judge to whom this case is assigned and  
16 his/her immediate family and court staff.

17 59. In the alternative, Plaintiff proposes the following Subclass:

18 **Arizona Subclass:** All individuals who attended a fertility clinic in Arizona  
19 and had one or more embryos cultured using any of the lots of Irvine  
Scientific's Oil for Embryo Culture identified in the April 1, 2023 Class 2  
Device Recall FujiFilm Oil for Embryo Culture notice.

20 60. Plaintiff reserves the right to, after conducting discovery, modify, expand or  
21 amend the above Class and Subclass definitions or to seek certification of a class or  
22 subclasses defined differently than above before any court determines whether  
23 certification is appropriate.

24 61. **Numerosity.** Consistent with Rule 23(a)(1), the members of the Class are  
25 so numerous and geographically dispersed that joinder of all Class members is  
26 impracticable. Plaintiff believes that there are hundreds of members of the Nationwide  
27 Class and in each of the Subclasses. The FDA recall notice estimated over 15,000 affected  
28 bottles of the Oil were in commerce at the time of the recall, indicating a significant



1 number of patients impacted by the defective oil overlay. Additionally, Class members  
2 may be identified through objective means via fertility clinic records. Class members may  
3 be notified of the pendency of this action by recognized, Court-approved notice  
4 dissemination methods, which may include U.S. mail, electronic mail, internet postings,  
5 and/or published notice.

6       **62. Commonality and Predominance.** Consistent with Fed. R. Civ. P. 23(a)(2)  
7 and with 23(b)(3)'s commonality and predominance requirements, this action involves  
8 common questions of law and fact which predominate over any questions affecting  
9 individual Class members. These common questions include, without limitation:

- 10           a. Whether the recalled lots of Irvine Scientific's Oil for Embryo Culture  
11           contained a defect that impaired or destroyed embryos;
- 12           b. Whether defect in the recalled lots of Irvine Scientific's Oil for  
13           Embryo Culture resulted from a manufacturing defect;
- 14           c. Whether Irvine Scientific is strictly liable for failing to timely recall  
15           the defective Oil for Embryo Culture;
- 16           d. Whether Irvine Scientific was negligent in failing to identify the  
17           defect in its Oil for Embryo Culture;
- 18           e. Whether Irvine Scientific was negligent in maintain adequate safety  
19           control and quality control measures in its manufacturing processes;
- 20           f. Whether the defect in its Oil for Embryo Culture resulted from Irvine  
21           Scientific's negligence;
- 22           g. Whether Irvine Scientific owed a duty to Plaintiff and class members  
23           to ensure its Oil for Embryo Culture was manufactured safely to  
24           ensure it would not harm embryos;
- 25           h. Whether Irvine Scientific knew or should have known that its  
26           manufacturing process resulted in or could produce Oil for Embryo  
27           Culture that was dangerous to embryos;
- 28           i. Whether Irvine Scientific breached a duty to Plaintiff and the Class  
              by distributing unsafe and dangerous Oil for Embryo Culture;
- j. Whether Irvine Scientific trespassed the chattels of Plaintiff and class  
              members by damaging their personal property—developing  
              embryos—through exposure to Defendants' defective Oil for Embryo  
              Culture;
- k. Whether Irvine Scientific was unjustly enriched through its conduct,

1           l.       Whether Plaintiff and the Class suffered harm as a result of Irvine Scientific's negligence, wrongful conduct, and other violations, and,

2           m.       Whether Plaintiff and the Class are entitled to relief.

3           63.    **Typicality.** Consistent with Fed. R. Civ. P. 23(a)(3), Plaintiff is a typical  
4 members of the Class. Plaintiff and the Class are each persons who obtained IVF  
5 treatment that resulted in fertilized eggs cultured using Irvine Scientific's Oil for Embryo  
6 Culture, which impaired, damaged, or destroyed the cultured embryos. Plaintiff's injuries  
7 are similar to other Class members and Plaintiff seeks relief consistent with the relief due  
8 to the Class.

9           64.    **Adequacy.** Consistent with Fed. R. Civ. P. 23(a)(4), Plaintiff is an adequate  
10 representative of the Class because Plaintiff are members of the Class and are committed  
11 to pursuing this matter against Irvine Scientific to obtain relief for themselves and for the  
12 Class. Plaintiff has no conflicts of interest with the Class. Plaintiff also has retained  
13 counsel competent and experienced in complex class action litigation of this type.  
14 Plaintiff intends to vigorously prosecute this case and will fairly and adequately protect  
15 the Class's interests.

16           65.    **Superiority.** Consistent with Fed. R. Civ. P. 23(b)(3), class action litigation  
17 is superior to any other available means for the fair and efficient adjudication of this  
18 controversy. Individual litigation by each Class member would strain the court system  
19 because of the numerous members of the Class. Individual litigation creates the potential  
20 for inconsistent or contradictory judgments and increases the delay and expense to all  
21 parties and the court system. By contrast, the class action device presents far fewer  
22 management difficulties and provides the benefits of a single adjudication, economies of  
23 scale, and comprehensive supervision by a single court. A class action would also permit  
24 customers to recover even if their damages are small as compared to the burden and  
25 expense of litigation, a quintessential purpose of the class action mechanism.

1 **CLAIMS**

2 **COUNT I**

3 **Strict Product Liability—Manufacturing Defect**

4 **(on behalf of Plaintiff and the Class)**

5 66. Plaintiff realleges the foregoing paragraphs as if fully set forth herein.

6 67. Irvine Scientific is strictly liable to Plaintiff and the Class for harm caused  
7 by manufacturing defects in its Oil for Embryo Culture.

8 68. Irvine Scientific is solely responsible for manufacturing, testing, supplying,  
9 distributing, and selling to fertility clinics the Oil for Embryo Culture used for Plaintiff's  
10 and the Class's IVF treatment.

11 69. Specifically, Irvine Scientific manufactures its Oil for Embryo Culture and  
12 sells the oil to IVF clinics for the express use of culturing embryos obtained via IVF.

13 70. The Oil for Embryo Culture was defective and, thus, unable to fulfill its  
14 express purpose of adequately culturing embryos for use in pregnancy. Upon  
15 manufacturing by Irvine Scientific, its Oil for Embryo Culture contained at least one  
16 defect that caused oil toxicity and differed from Irvine Scientific's intended oil, which  
17 failed to conform to Irvine Scientific's designs, specifications, or other typical units of its  
18 oil.

19 71. Consequently, the oil was unable to aid in the culturing of embryos—its  
20 express and sole purpose—and instead, impaired, destroyed, or damaged the embryos.

21 72. Irvine Scientific's defective Oil for Embryo Culture was used in an attempt  
22 to culture Plaintiff's and the Class's embryos. However, due to the manufacturing defect,  
23 Plaintiff and the Class lost their embryos or they were irreparably damaged.

24 73. Plaintiff and the Class suffered substantial harm as a result of the defect,  
25 including, among other things, financial and economic harm, loss property, lost  
26 opportunity of achieving a pregnancy, and serious and last emotional distress.

27 74. Plaintiff and the Class seek all remedies available for Irvine Scientific's  
28 manufacturing defect.

**COUNT II**

**Strict Product Liability—Failure to Warn**

**(on behalf of Plaintiff and the Class)**

75. Plaintiff realleges the foregoing paragraphs as if fully set forth herein.

76. Plaintiff brings this strict liability claim against Irvine Scientific for its failure to warn.

77. At all relevant times, Irvine Scientific engaged in the business of testing, developing, designing, manufacturing, marketing, selling, distribution, and promoting its Oil for Embryo Culture, which, due a defect, was unreasonably dangerous and impaired, damaged, and destroyed the embryos it was intended to culture.

78. Because Irvine Scientific researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce the Oil for Embryo Culture, it had a duty to warn of the risks associated with the use of its Oil for Embryo Culture, and to identify and disclose any defects that may cause harm.

79. At all times relevant, Irvine Scientific had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, distribute, maintain, supply, provide proper warnings, and take such steps as necessary to ensure that the Oil for Embryo Culture did not cause users and consumers to suffer from unreasonable and dangerous risks.

80. Additionally, Irvine Scientific's Oil for Embryo Culture had potential risks that Irvine Scientific knew or should have known, including that oil toxicity would inhibit or entirely prevent embryos from culturing, destroying them or irreparably damaging the embryos. Those risks were known or knowable due to the scientific and medical knowledge that was generally accepted in the scientific community at the time of the manufacture, distribution, or sale of the Oil for Embryo Culture.

81. Irvine Scientific's Oil for Embryo Culture, however, was defective and unreasonably dangerous when it left Irvine Scientific's possession because it did not

1 contain adequate warnings, including warnings concerning the risk of defect that its  
2 formulation was toxic and would stop embryos development.

3 82. The risks of a defect in its Oil for Embryo Culture were well known to Irvine  
4 Scientific, including the possibility that it would impair or destroy embryos. Irvine  
5 Scientific knew and in fact intended that its Oil for Embryo Culture would come into  
6 contact with embryos and designed the Oil for Embryo Culture to protect and stabilize  
7 culturing embryos as the embryos developed further. However, the Oil for Embryo  
8 Culture presented a substantial and foreseeable danger to embryos should it be misused,  
9 be toxic, or contain other defects.

10 83. Ordinary patients would not have recognized the potential for risks and, in  
11 fact, often did not know the brand or type of any solution used to develop the embryos or  
12 any details about the method by which culture media and oil overlays would facilitate  
13 growth or might cause harm. Irvine Scientific, thus, had unique knowledge that patients  
14 did not, including the adequate quality control measures necessary to prevent or identify  
15 any defects in the Oil for Culture Media.

16 84. Irvine Scientific thus, had an obligation to warn patients but failed to  
17 adequately do so or to instruct patients of the potential risks of applying the Oil for  
18 Embryo Culture to embryos. A reasonable manufacturer, distributor, or seller under  
19 similar circumstances would have warned of the danger or instructed in the safe use of  
20 the oil overlays.

21 85. Irvine Scientific had constructive notice or knowledge and knew, or in the  
22 exercise of reasonable care should have known, that the Oil for Embryo Culture was  
23 dangerous, had risks, was defective in manufacture or design, including that it would  
24 destroy and prevent the development of embryos with which it would come into contact.  
25 Irvine Scientific, however, failed to adequately warn or instruct of the potential risks of  
26 applying its defective Oil for Embryo Culture to human reproductive material.

1 86. Irvine Scientific knew or should have known that failure to adequately warn  
2 about the risks of its Oil for Embryo Culture would cause irreparable harm to those  
3 embryos that were treated with the Oil.

4 87. Irvine Scientific's defective Oil was used in an attempt to culture Plaintiff's  
5 and the Class's embryos. However, due to the manufacturing defect, Plaintiff and the  
6 Class lost their embryos, or they were irreparably damaged.

7 88. Plaintiff and the Class suffered substantial harm as a result of the defect,  
8 including, among other things, financial and economic harm, lost property, lost  
9 opportunity of achieving a pregnancy, and serious and lasting emotional distress.

10 89. Plaintiff and the Class seek all remedies available for Irvine Scientific's  
11 manufacturing defect.

12 **COUNT III**

13 **Negligence**

14 **(on behalf of Plaintiff and the Class)**

15 90. Plaintiff realleges the foregoing paragraphs as if fully set forth herein.

16 91. At all relevant times, Irvine Scientific was responsible for testing,  
17 developing, designing, manufacturing, marketing, selling, distribution, inspecting, and  
18 promoting its Oil for Embryo Culture, and as such, owed Plaintiff and the Class—those  
19 whose embryos would be cultured with the use of the Oil for Embryo Culture—a duty to  
20 exercise reasonable care.

21 92. Irvine Scientific fully understood that its Oil for Embryo Culture was  
22 effective when it was nontoxic. Consequently, Irvine Scientific knew or should have  
23 known that failure to ensure the nontoxicity of the Oil would impede the ability of  
24 embryos to develop and could damage or destroy them. Irvine Scientific, therefore, knew  
25 or reasonably should have known that the Oil for Embryo Culture needed to be designed,  
26 produced, manufactured, assembled, maintained, inspected, sold, and supplied properly,  
27 without defects and with due care, to be safely applied to any embryos.

1           93. As an entity that is active in fertility treatment products, Irvine Scientific  
2 also understood the sensitive and emotional nature of IVF treatment and the emotional  
3 burden infertility and IVF impose on patients. Irvine Scientific further knew that Plaintiff  
4 and the Class were particularly susceptible to emotional distress and other emotional and  
5 mental harms due to the emotional distress of infertility and IVF treatment. Finally, Irvine  
6 Scientific understood the financial and physical burden of IVF, and that inadequate oils  
7 for culturing embryos would undermine the time, effort, and expense of patients' IVF  
8 treatment.

9           94. Given the risks of defective oil overlay for the embryos and fertility patients,  
10 Irvine Scientific owed a duty to Plaintiff and the Class to manufacture, inspect, test, and  
11 implement adequate quality controls to ensure that its Oil for Embryo Culture was safe  
12 and effective for development of human embryos and that the use of the Oil for Embryo  
13 Culture would not damage, impair, or destroy those embryos.

14           95. Similarly, because Irvine Scientific manufactures products used in fertility  
15 treatment and for the culturing of irreplaceable, and sensitive embryos, Irvine Scientific  
16 assumed a duty to Plaintiff and the Class to ensure any product used in culturing was  
17 safe.

18           96. Despite this, Irvine Scientific negligently, recklessly, and carelessly failed  
19 to use reasonable care in the production, manufacturing, testing, inspecting, and  
20 implementing adequate quality control concerning its Oil for Embryo Culture. As a result,  
21 its Oil for Embryo Culture was not fit for use in culturing embryos but instead caused  
22 significant and irreparable damage to those embryos.

23           97. Furthermore, Irvine Scientific failed to timely warn its customers of the  
24 dangers of its defective Oil, exacerbating the harm caused by the defect by allowing  
25 fertility clinics to continue using the Oil for Embryo Culture even when Irvine Scientific  
26 knew or should have known it would cause harm.



1           98. Irvine Scientific's conduct is a significant departure from what a reasonable  
2 entity or person overseeing products used in the development of embryos would do given  
3 the high emotional and physical toll of infertility and IVF treatment.

4           99. As a direct and proximate result of Irvine Scientific's negligence, including  
5 but not limited to its failure to reasonably produce, manufacture, inspect, test, and  
6 implement adequate quality control concerning its Oil for Embryo Culture, Plaintiff and  
7 the Class were harmed. Specifically, due to the defective Oil for Embryo Culture,  
8 Plaintiff and the Class suffered, among other things: (1) loss in the economic value of  
9 their IVF treatment, which was undermined by the damage to and destruction of the  
10 embryos obtained through IVF; (2) loss of the their embryos and the opportunity for a  
11 potential pregnancy; (3) emotional harm and distress from the loss of the embryos; and  
12 (4) incurred additional financial costs for further fertility or mental health treatment.

13           100. Irvine Scientific's negligence substantially caused Plaintiff's and the Class's  
14 harms because the Oil for Embryo Culture damaged and destroyed Plaintiff's and the  
15 Class's embryos and prevented those embryos from having the opportunity to develop to  
16 the blastocyte stage, where they could be transferred for an attempted pregnancy.

17           101. Irvine Scientific acted willfully, wantonly, and with a conscious disregard  
18 for the safety of fertility patients, like Plaintiff and the Class, who Irvine Scientific knew  
19 would submit their embryos for culturing using the Oil for Embryo Culture. This is  
20 especially true because Irvine Scientific knew of the substantial and harmful  
21 consequences of unsafe culturing products on the survival of the embryo and the  
22 emotional and financial health of the fertility patients.

23           102. Irvine Scientific's defective oil was used in an attempt to culture Plaintiff's  
24 and the Class's embryos. Due to Irvine Scientific's negligence, Plaintiff and the Class  
25 lost their embryos or they were irreparably damaged.

26           103. Plaintiff and the Class suffered substantial harm as a result of Irvine  
27 Scientific's negligence, including, among other things, financial and economic harm, lost  
28

1 property, lost opportunity of achieving a pregnancy, and serious and lasting emotional  
2 distress.

3 104. Plaintiff and the Class seek all remedies available for Irvine Scientific's  
4 negligence.

5 **COUNT IV**

6 **Negligent Failure to Recall**

7 **(on behalf of Plaintiff and the Class)**

8 105. Plaintiff realleges the foregoing paragraphs as if fully set forth herein.

9 106. Irvine Scientific manufactured, tested, distributed, and sold defective bottles  
10 of its Oil for Embryo Culture to fertility clinics throughout the United States. The  
11 defective Oil for Embryo Culture was later used during Plaintiff's and the Class's IVF  
12 treatment to culture the retrieved and fertilized embryos.

13 107. Irvine Scientific negligently recalled the defective Oil for Embryo Culture  
14 by failing to timely implement the recall. Irvine Scientific knew or reasonably should  
15 have known that its Oil for Embryo Culture would damage or destroy embryos if the Oil  
16 for Embryo Culture was not consistent with Irvine Scientific's specifications.

17 108. Irvine Scientific, furthermore, should have known that use of defective Oil  
18 for Embryo Culture would not only destroy embryonic cells, but would furthermore cause  
19 significant harm to fertility patients, both emotionally and financially, and render  
20 worthless patients' extensive and burdensome IVF treatments.

21 109. Consequently, Irvine Scientific understood the need to immediately and  
22 effectively issue a recall of any defective Oil for Embryo Culture to prevent its use in any  
23 treatment and to regularly test and monitor the Oil for Embryo Culture it manufactured  
24 to ensure it met any required specifications to be an effective solution for use during  
25 embryo growth.

26 110. Despite that, Irvine Scientific continued to sell the defective Oil for Embryo  
27 Culture, including to fertility clinics that treated Plaintiff and the Class, when it knew or  
28 should have known based on feedback from fertility medical providers that its Oil for

1 Embryo Culture contained a defect and after it had failed to adequately implement quality  
2 control measures necessary to ensure the Oil for Embryo Culture satisfied the  
3 specifications and was adequately formulated to facilitate embryo growth.

4 111. A reasonable manufacturer, distributor, or seller facing the same or similar  
5 circumstances as Irvine Scientific would have recalled the defective oil overlay to prevent  
6 harm to fertility patients or their embryos.

7 112. Irvine Scientific's failure to timely recall the defective oil overlay caused  
8 harm to Plaintiff and Class members. Had Irvine Scientific recalled the defective Oil for  
9 Embryo Culture before it was used on Plaintiff's and the Class's embryos, Plaintiff's and  
10 the Class's embryos would not have been damaged or destroyed by the oil.

11 113. Because Irvine Scientific failed to timely recall its Oil for Embryo Culture,  
12 the oil was used in an attempt to culture Plaintiff's and the Class's embryos. Due to a  
13 defect in the Oil for Embryo Culture, Plaintiff and the Class lost their embryos or they  
14 were irreparably damaged.

15 114. Plaintiff and the Class suffered substantial harm as a result of Irvine  
16 Scientific's negligent notice and recall of the defective Oil for Embryo Culture, including,  
17 among other things, financial and economic harm, lost property, lost opportunity of  
18 achieving a pregnancy, and serious and lasting emotional distress.

19 115. Plaintiff and the Class seek all remedies available for Irvine Scientific's  
20 negligent failure to recall its Oil for Embryo Culture.

21 **COUNT V**

22 **Trespass to Chattels**

23 **(on behalf of Plaintiff and the Class)**

24 116. Plaintiff realleges the foregoing paragraphs as if fully set forth herein.

25 117. Plaintiff and the Class owned and had a right to possess their reproductive  
26 materials, including their developing embryos. Irvine Scientific's Oil for Embryo Culture  
27 damaged and destroyed Plaintiff's and the Class's embryos.

1 118. Irvine Scientific intentionally interfered with Plaintiff's and the Class's  
2 possession of their embryos by manufacturing a defective product that destroyed the  
3 embryos instead of creating a safe environment for the embryos to grow and develop.  
4 Irvine Scientific further interfered by failing to timely recall the defective solution or to  
5 warn about the dangers of the Oil for Embryo Culture before its use in the culturing of  
6 Plaintiff's and the Class's embryos.

7 119. Plaintiff and the Class did not consent to or authorize the use of faulty and  
8 defective oil overlays on their developing embryos.

9 120. Irvine Scientific's Oil for Embryo Culture damaged Plaintiff's and the Class  
10 personal property when, due to a defect, the Oil for Embryo Culture damaged, impaired,  
11 or destroyed the embryos, preventing their use in an attempted pregnancy.

12 121. Irvine Scientific impaired the condition, quality, or value of Plaintiff's and  
13 the Class's personal property because the defective Oil for Embryo Culture impaired the  
14 opportunity for the embryos to develop sufficiently for an attempted pregnancy.

15 122. Irvine Scientific's interference with Plaintiff's and the Class's embryos  
16 caused them harm, including loss of their embryos, financial and economic harm, and  
17 serious and lasting emotional harm. The harm Plaintiff and the Class suffered was a direct  
18 and foreseeable result of Irvine Scientific's formulation of defective oil overlays for  
19 culturing embryos.

20 123. Plaintiff and the Class seek all remedies available for Irvine Scientific's  
21 negligent failure to recall its Oil for Embryo Culture.

22 **COUNT VI**

23 **Unjust Enrichment**

24 **(on behalf of Plaintiff and the Class)**

25 124. Plaintiff realleges the foregoing paragraphs as if fully set forth herein

26 125. Plaintiff and the Class conferred a tangible and material economic benefit  
27 on Defendants by paying fertility clinics that used, and paid Irvine Scientific for, the Oil  
28

1 for Embryo Culture. At least part of Plaintiffs and the Class's fertility treatment payments  
2 went to Irvine Scientific, and Irvine Scientific readily accepted those benefits.

3 126. Had Plaintiff and the Class known of Irvine Scientific's defective Oil for  
4 Embryo Culture or its inadequate measures for ensuring that the Oil for Embryo Culture  
5 met required specifications and was formulated adequately—including, among other  
6 things, failing to adequately inspect, test, formulate, and implement quality controls—  
7 Plaintiff and the Class would not have paid for the use of the Oil for Embryo Culture.

8 127. Any benefit Irvine Scientific obtained from the sale and purchase of its  
9 defective Oil for Embryo Culture was unfairly and wrongfully obtained. Although Irvine  
10 Scientific represented that its Oil for Embryo Culture would help promote the  
11 development of embryonic growth, it did the opposite, destroying, damaging, and  
12 impairing the viability of the embryos.

13 128. Further, Irvine Scientific knew or should have known that the benefit it  
14 received from the sale and purchase of its Oil for Embryo Culture was obtained under the  
15 expectation that the Oil for Embryo Culture would have the ability to aid in the process  
16 of embryonic growth.

17 129. Permitting Irvine Scientific to retain the benefit it received from the sale and  
18 purchase of its defective Oil for Embryo Culture would be unjust and inequitable.

19 130. Plaintiff and the Class are entitled to restitution and to recover from Irvine  
20 Scientific any amount unfairly and wrongfully obtained via the sale of its defective Oil  
21 for Embryo Culture to Plaintiff and the Class.

22 **PRAYER FOR RELIEF**

23 WHEREFORE, Plaintiff, individually and on behalf of the Class, pray for the  
24 following relief:

- 25 a. An Order certifying the Classes as defined above, appointing Plaintiff as  
26 Class representatives, and appointing Plaintiff's counsel as Class counsel;  
27 b. An award of all recoverable compensatory, statutory, and other damages  
28 sustained by Plaintiff and Class Members;

- c. Equitable relief including disgorgement, unjust enrichment, and all other available relief under applicable law;
- d. Reasonable attorneys' fees and expenses as permitted by applicable law;
- e. Pre- and post-judgment interest as allowed by law; and,
- f. Such further relief at law or in equity that this Court deems just and proper.

**DEMAND FOR JURY TRIAL**

Plaintiff demands a trial by jury on all issues so triable.

**ZIMMERMAN REED LLP**

Dated: November 26, 2024

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